

Appl. No. 09/915,580

LIST OF CLAIMS

Claim 1. (Previously Presented) A whole blood immunoassay comprising the steps of:

mixing a whole blood sample with sensitized insoluble carrier particles to cause an immune agglutination;

diluting the resulting agglutination mixture with an aqueous solution containing an erythrocyte lysing agent to lyse erythrocytes; and

determining a degree of agglutination of the resulting whole blood sample.

Claim 2. (Original) A whole blood immunoassay according to Claim 1, wherein the erythrocyte lysing agent is a surfactant.

Claim 3. (Original) A whole blood immunoassay according to Claim 2, wherein the surfactant is sodium dodecyl sulfate.

Claim 4. (Previously Presented) A whole blood immunoassay according to Claim 1, wherein the degree of agglutination of the assay sample is conducted by flow cytometry.

Appl. No. 09/915,580

Claim 5. (Previously Presented) A whole blood immunoassay according to Claim 4, further comprising the steps of:

introducing the resulting whole blood sample including unagglutinated particles and agglutinated particles to a flow cell, irradiating particles passing through the flow cell with laser light, and detecting scattered light generated thereby;

setting a threshold value for distinguishing unagglutinated particles from agglutinated particles with regard to intensity of the scattered light; and

distinguishing and counting the unagglutinated particles and the agglutinated particles in reference to the threshold value; and

calculating the degree of agglutination from the number of unagglutinated particles and the number of agglutinated particles.

Claim 6. (Original) A whole blood immunoassay according to Claim 5, wherein the degree of agglutination is calculated by the number of agglutinated particles  $P$  / (the number of agglutinated particles  $P$  + the number of unagglutinated particles  $M$ ).

Claim 7. (Original) A whole blood immunoassay according to Claim 5, wherein the scattered light is forward scattered light.

Appl. No. 09/915,580

Claim 8. (Original) A whole blood immunoassay according to Claim 1, wherein the size of the insoluble carrier particles is 0.1  $\mu\text{m}$  to 20  $\mu\text{m}$ .

Claim 9. (Original) A whole blood immunoassay according to Claim 1, wherein a mixture ratio of the whole blood sample to the insoluble carrier particles is 1:5 to 1:20.

Claim 10. (Original) An immunoassay according to Claim 1, wherein, in the immune agglutination of the whole blood sample with the insoluble carrier particles, the reaction temperature is from 20 to 50°C and the reaction time is from 15 seconds to 20 minutes.

Claim 11. (Previously Presented) A whole blood immunoassay comprising the steps of:

mixing a whole blood sample, which comprises an antigen and an antibody, with immuno-sensitized insoluble carrier particles to cause an immune agglutination prior to adding a lysing agent;

diluting the resulting agglutination mixture with an aqueous solution containing an erythrocyte lysing agent to lyse erythrocytes; and

Appl. No. 09/915,580

determining a degree of agglutination of resulting whole blood sample.

Claim 12. (NEW) The whole blood immunoassay of claim 1, wherein the degree of agglutination of the resulting whole blood sample is determined by a PAMIA apparatus.

Claim 13. (NEW) The whole blood immunoassay of claim 11, wherein the degree of agglutination of the resulting whole blood sample is determined by a PAMIA apparatus.